

Pathogen Reduction - *Salmonella*

OBJECTIVES

To demonstrate mastery of Pathogen Reduction the trainee will:

1. Explain why *Salmonella* testing is used.
2. State who will conduct *Salmonella* testing.
3. Describe how and when *Salmonella* samples are taken.
4. Take appropriate actions when there is a *Salmonella* set failure for Set A, Set B, and Set C.
5. Obtain completed *Salmonella* results from LEARN.

SALMONELLA TESTING

Testing is conducted in plants by FSIS personnel, who collect both carcass and ground product samples.

The Agency's *Salmonella* performance standards for raw meat and poultry and for raw ground products are in §310.25 and §381.94. The goal of the *Salmonella* testing program is to protect the consumer from contaminated products, especially from fecal contamination, by verifying that each establishment's performance meets the *Salmonella* standards.

The Agency searched for an organism that could be detected using modern microbiological techniques. *Salmonella* was selected as the target organism because it is a commonly reported cause of foodborne illness and is present to varying degrees in all major species. Also, current lab methods can recover *Salmonella* from a variety of meat and poultry products.

FSIS requires that beef, swine, and chicken carcasses be sampled for *Salmonella* testing. There are no published performance standards for turkey carcasses. However, samples are being requested for data collection. Ground products, including ground beef, ground chicken, and ground turkey, are also sampled. The *Salmonella* testing performance standards set for industry are regulatory requirements.

Salmonella samples are collected using the sponge technique from beef, swine, and turkey carcasses. Sponge sites are the same as those used for *E. coli* sampling.

- For beef, the sample sites are the flank, the brisket, and the rump.
- For swine, they are the belly, ham, and jowls.
- For turkey, the sites are back & thigh.

Chickens are sampled using whole bird rinses.

Ground samples consist of 25 grams of the ground product.

The Agency might require that either the carcass or the ground product derived from carcasses be sampled in a single establishment that produces both products. However, both types of product are not sampled at the same time.

Performance Standards

The pathogen reduction performance standard applies to establishments, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting *Salmonella* contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* samples.

Salmonella performance standards are regulatory requirements. Samples are taken in sets and the results of an entire set are used to determine if an establishment is meeting the performance standards. So failure to meet *Salmonella* performance standards is based on whether or not a set passes, not on individual samples. The chart below shows the number

of samples required to complete a sample set for the different species, and the maximum number of positive results allowed before a set fails to meet the regulatory standards. A *Salmonella* test is positive when any *Salmonella* organisms are found.

SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (% positive for <i>Salmonella</i>)	Number of samples tested (n)	Maximum number of positives [allowed] to achieve Standard (c)
Steers/heifers	1.0	82	1
Cows/bulls	2.7	58	2
Ground beef	7.5	53	5
Hogs	8.7	55	6
Fresh pork sausages	N/A	N/A	N/A
Broilers	20.0	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	N/A	N/A	N/A

The chart above, taken from the regulations, shows that the performance standards specify a maximum number of positive test results (c) permitted in a specified number of samples (n) for each species and category of raw product. Here's how to use this chart. Consider steers and heifers. The performance standard is set at 1%. To meet this standard an establishment can have no more than one positive sample result (c) out of every set of 82 carcasses (n) sampled.

***Salmonella* Workshop**

1. Select from the list below the species and types of product that must be tested for *Salmonella* performance standards.

- | | |
|--|---|
| <input type="checkbox"/> Beef carcasses | <input type="checkbox"/> Ground chicken |
| <input type="checkbox"/> Chicken carcasses | <input type="checkbox"/> Ground pork |
| <input type="checkbox"/> Duck carcasses | <input type="checkbox"/> Ground turkey |
| <input type="checkbox"/> Equine carcasses | <input type="checkbox"/> Sheep carcasses |
| <input type="checkbox"/> Geese carcasses | <input type="checkbox"/> Swine carcasses |
| <input type="checkbox"/> Goat carcasses | <input type="checkbox"/> Turkey carcasses |
| <input type="checkbox"/> Ground beef | |

2. Why is *Salmonella* testing done by FSIS?

Procedure 05A03

The IIC receives sampling supplies and a schedule of products from which to collect samples. FSIS personnel conduct procedure 05A03 according to the schedule by collecting samples at an unannounced time each day the product is produced until enough samples have been taken and analyzed to constitute a set of samples. Once collected, samples are sent to the FSIS lab for testing. *Salmonella* test results only show the presence of the organism, not the number of organisms. If any *Salmonella* is found in the sample, the test result is positive.

FSIS inspection personnel should collect *Salmonella* samples in accordance with the step-by-step directions found in FSIS Directive 10,230.5. Samples are sent to the FSIS laboratories indicated on the form via Federal Express. The lab analyzes the samples and the Office of Public Health and Science tracks the data and results. Attachment 1 in this module describes the procedure for collecting samples.

Salmonella sampling is a directed sampling procedure. It is documented as an unscheduled 05A03 on the Process Schedule and recorded as performed.

How to Get *Salmonella* Supplies and Sample Forms

When a sample set is scheduled but inadequate quantities of supplies or forms are received, the program employee should request additional materials. To obtain additional sampling supplies, e-mail the laboratory that sent the supplies. The employee should send an Outlook message using one of the following addresses.

Sampling Supplies – Eastern Laboratory
Sampling Supplies – Midwestern Laboratory
Sampling Supplies – Western Laboratory

For additional forms, program employees should request them in an Outlook message addressed to Sampling Forms - Headquarters.

How to Retrieve Sample Set Information from LEARN

When sets are complete, the test results are posted in the Laboratory Electronic Application for Results Notification System (LEARN). Employees may access LEARN on FAIM computers. After logging onto the intranet, the employee can view *Salmonella* data by going to the following address:

<http://dchqintra/learn/welcome1.cfm>

Individual sample results will be posted on LEARN only after the set is complete. Information regarding individual sample results or individual establishment results can be accessed by following these instructions.

Click on the web address listed above
Enter the establishment number
Click on Submit
Click on Check for PR/HACCP Completed Set Results
Click on Pass or Fail to see individual results

PREP Reports

The Pathogen Reduction Enforcement Program (PREP) is a database maintained by the Office of Public Health and Science (OPHS). Numerous reports are generated and made available to the District Office regarding *Salmonella* sample set collection and results.

DESCRIPTION OF PATHOGEN REDUCTION ENFORCEMENT PROGRAM (PREP) REPORTS

- Schedule Report – This report notifies the District Manager (DM) and Frontline Supervisor (FS) of establishments within their jurisdiction that have been mailed forms and supplies for *Salmonella* compliance testing. This report should be shared with the field inspection team to alert them to the scheduled sampling. Sample collection can be verified by the FS through the Laboratory Electronic Application for Results Notification (LEARN) FSIS Intranet site.
- Early Warning of Set Failure – This report identifies an establishment when the number of positive *Salmonella* samples for the current sample set has exceeded half of the maximum number of positives allowed.

There are two slightly different variations in the text of this report. One report gets sent for “A” and “B” sets; the other gets sent for “C” and higher sets. The DO must read the statement on the report to establishment management.

- Set Full Report – This report notifies the DM, FS, and inspection personnel that sufficient analyzable samples have been received in the lab to complete the sample set.
- Completed Set Report – This report notifies the DM, FS, and establishment management that the set analysis is complete and whether the set passed or failed to meet the *Salmonella* performance standard for the tested product. This report is also accessible to the IIC at the establishment through LEARN. The IIC should share report results with establishment management.
- Testing Eligibility Report – This report periodically identifies establishments under a DM's and FS's jurisdiction that are eligible for *Salmonella* performance standard compliance sampling and the class of product produced at the establishment. The report gives the FS working with the field team an opportunity to verify and make

corrections to the information. If corrections are needed, the FS should e-mail all the pertinent information to the [OPHSPrep](#) Outlook mailbox.

- Non-Responders Report – This report periodically identifies the establishments under a DM's and FS's jurisdiction that are scheduled for sampling but have not provided a sample or feedback in the previous 30 days. The DM should be able to account for each establishment on this list and be able to support the absence of sampling during this period.
- Current Testing Status Report - This report periodically identifies the establishments under a DM's and FS's jurisdiction that are scheduled for sampling. It also provides the current set status, when sample collection began, how many samples have been analyzed to date, as well as when the most recent sample was submitted.
- Product No Longer Produced Report – This report notifies the District when a sample form from an establishment is returned to the laboratory stating the product is no longer produced at the establishment. The sample set for this project code has been terminated with a "NLP" set result in PREP. If the form was submitted in error to the laboratory, all the pertinent information should be e-mailed to the [OPHSPrep](#) Outlook mailbox to make a correction to the PREP database.

***Salmonella* Sets**

Sample results are kept in sets. If the sample set meets the *Salmonella* performance standards, it passes. Sets that exceed the standards fail.

***Salmonella* Set Definitions**

FSIS laboratories keep records of *Salmonella* test set results. Sets are described using the following terms.

- Set A is the first set of samples taken in a plant or one taken when the previous set passed.
- Set B is the set of samples taken after failure of one set (Set A) immediately prior to this set.
- Set C is the set of samples taken when two consecutive previous sets (Sets A and B) have failed.

***Salmonella* Set A Failures**

When there is a Set A failure, the District Manager (DM) sends a letter containing the following information to the establishment:

- The set completion date listed on the PREP report.
- The class of product.
- The sample test results (e.g., number of samples analyzed and number of positive samples in the set).
- A statement that the establishment needs to take immediate action to meet the standard in accordance with sections 310.25(b)(3)(i) or 381.94(b)(3)(i) of the regulations.
- A request for the establishment to respond to the Supervisory Veterinary Medical Officer (SVMO)/IIC to explain why it believes that it is operating in full compliance with the regulations or what immediate actions it intends to take.

Within 30 days of the date of the DM's letter:

- The IIC will document the establishment's response to the DM's letter (i.e., corrective actions identified or an explanation of compliance). The IIC will maintain a copy of the documentation in the inspection files.
- The frontline supervisor and IIC will conduct and document an assessment of the establishment's HACCP and SSOP procedures and, where applicable, analyze data from the establishment's generic *E. coli* testing program, focusing on the corrective and further planned actions by the establishment. The IIC will maintain a copy in the inspection files.
- The frontline supervisor and IIC will develop, document, and implement a verification plan, using the 01 and 02 SSOP and HACCP procedure codes, to verify any

corrective actions implemented by the establishment. The IIC and CSI will conduct verifications to evaluate the effectiveness of corrective actions. The IIC will keep a copy in the inspection files.

- After the IIC and frontline supervisor have completed the above documents, the frontline supervisor will forward them to the DM.
- The frontline supervisor and IIC will correlate with in-plant inspection program personnel to ensure the plan is understood and executed. Based on findings of the verification activities, any warranted enforcement actions will be taken in accordance with the rules of practice (9 CFR Part 500). The frontline supervisor will inform the DM about any necessary enforcement action.
- The frontline supervisor, IIC, and in-plant inspection program personnel will consult with the Technical Service Center (TSC) for assistance in data analysis or technical questions that arise.

Collection of samples for set B (the next *Salmonella* set) begins immediately after an establishment completes corrective and preventive actions or within 60 days of the end of set A, unless an agreement between the DM and the establishment was made to allow more time to implement corrective and preventive actions. The DM communicates with the frontline supervisor and the IIC to ensure that the establishment progresses with their actions in a timely manner.

***Salmonella* Set B Failures**

When there is a Set B failure:

- The DM sends a letter to the establishment with the same specific sample information as that included in a Set A failure. The letter informs the establishment that FSIS expects the establishment to address its total food safety program by reassessing its HACCP plan for that product and taking appropriate corrective and preventive actions and by making any necessary corrective actions in its SSOP.
- The DM, in consultation with the frontline supervisor, IIC, and inspection program personnel, will determine whether the establishment conducted proper reviews of its total food safety program, including a reassessment of HACCP plans and necessary evaluation of the effectiveness of the SSOP. The DM will issue a Notice of Intended Enforcement (NOIE) action if the reassessment is not performed.
- After the establishment has performed a reassessment, validated modifications to the plan, and reevaluated and modified the SSOP, as necessary, the DM will initiate an In-Depth Verification (IDV) review. The DM will receive the report developed from the IDV, containing the team's findings. The DM's designee will analyze the findings and make recommendations about how to proceed. FSIS may also decide to conduct an IDV at some or all of the establishment's suppliers.
- The DM makes one of the following decisions:

- If the establishment's actions addressing its total food safety program do not meet the requirements in the regulations, the DM will issue an NOIE.
 - If the establishment's actions addressing its total food safety program raise concerns regarding the establishment's design and execution of the program, but the concerns do not indicate regulatory noncompliance, the DM will send a 30-day reassessment letter that outlines FSIS concerns. The 30-day reassessment letter will ask the establishment to produce records that address the concerns.
 - If the establishment's actions addressing its total food safety program in response to the IDV meet the requirements in the regulations, or if in response to the NOIE or the 30-day reassessment letter, the establishment provides adequate evidence that it has not failed to meet the requirements in the regulations, the DM will schedule Set C to verify the successful operation of the establishment's total food safety program.
- The enforcement investigation and analysis officer (EIAO) develops a verification plan to be used by in-plant inspection program personnel to verify all modifications made by the establishment in response to the Set B failure and to assess corrective actions and further planned actions provided in response to an enforcement action. The EIAO sends a copy of the verification plan to the frontline supervisor and DM and a copy will be kept in the inspection files at the establishment.
 - The IIC and CSI will conduct verifications to evaluate the effectiveness of establishment's actions. The EIAO, frontline supervisor, IIC, and in-plant inspection program personnel correlate to ensure the verification plan is fully understood and executed as intended.
 - The frontline supervisor e-mails a report to the DM each month on the findings of the verification activities until the establishment has passed the next *Salmonella* sample set.

Collection of samples for set C begins immediately after an establishment completes corrective and preventive actions or within 90 days of the end of set B, unless an agreement between the DM and the establishment allows more time to implement modifications. The DM communicates with the frontline supervisor and the IIC to ensure that the establishment progresses with their actions in a timely manner.

***Salmonella* Set C Failures**

When there is a Set C failure:

- The DM sends a letter to the establishment with the specific sample information. The letter informs the establishment that FSIS will instruct a EIAO and a compliance officer (CO) to conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed Set C.

- The EIAO and a CO focus on the reassessments and corrective and preventive actions that the establishment took after the Set B failure, and on whether there is a basis to find that the establishment's total food safety program is not adequate. The EIAO and the CO consult with the IIC and frontline supervisor. If the establishment requests, the EIAO and the CO will meet with the establishment and provide an opportunity for the plant to present evidence about why it believes it has not failed to meet the regulatory requirements. If warranted, the CO develops a case file for an enforcement action. For grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.
- Based on findings by the EIAO and the CO, the DM and officials from Headquarters will determine what actions the Agency will take, including enforcement actions.
- There may be rare instances in which the DM determines that the establishment should conduct an additional reassessment. In such cases, the DM will issue a 30-day reassessment letter, and the IIC and CSI will conduct in-plant verifications and follow-up *Salmonella* verification testing will occur.

FSIS adopted pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effectively reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods.

Pathogen Reduction – *Salmonella* examples:

Example 1:

You are a CSI assigned to a large, two-shift broiler slaughter operation. Today, you receive shipping containers and sampling supplies from the Eastern Laboratory for *Salmonella* Performance Standard sampling set for broilers. Yesterday you received a set of FSIS 10,210-7 forms. As the IIC's designee for sample collection, you are aware that *Salmonella* sampling is a directed sampling procedure. You perform procedure 05A03 according to the schedule by collecting samples at an unannounced time each day the product is produced.

Several months have elapsed since you were directed to collect samples. Throughout the sampling process, you have tracked the progress through daily monitoring of LEARN for sample receipt. You have submitted 53 samples to date. The 53rd sample was sent yesterday. LEARN indicates that two have been discarded.

Is it time to stop sampling?

Answer:

No. Do not stop sampling until the District notifies you that the sample set is complete. (Set Full Report has been received).

Example 2:

You are an IIC/CSI at Est. 00038M, a mature cattle slaughter plant. The plant is currently in the process of being sampled for cows/bulls *Salmonella* performance standard testing. Plant management tells you that they received a call from the District Office informing them that the District Office was sent an Early Warning of Set Failure report concerning Est. 00038M. This report indicated that the positive results for this sample set are currently one over the 50% of the maximum number of positives allowed for meeting the standard. The District Office also told plant management that this call will serve as an "early warning" notification that the plant is on target to fail this set.

Plant management recognizes the serious nature of the call. The plant establishes additional anti-microbial intervention measures after a reassessment of its 03J HACCP plan. The plant requests a suspension of the current *Salmonella* sampling program to allow them a "reasonable period of time to validate the efficacy of the newly established measures". They respectively request that FSIS stops sampling for a month.

After consideration of the rationale provided by plant management, what actions should you take?

Answer:

You consider the rationale provided by plant management. You inform plant management that reassessment and modification is appropriate, but the collection of the sample set continues until completion. The early warning is provided so that the plant can make modifications if it chose to do so.

***Salmonella* Workshop**

3. How do inspectors document the *Salmonella* sampling procedure?

4. After a *Salmonella* Set A failure, who takes each of the following actions?
(More than one answer may apply.)

- a. DM
- b. IIC
- c. Frontline Supervisor
- d. CSI

- _____ Sends notification letter to the establishment
- _____ Documents the establishment's response to the letter
- _____ Conducts and documents assessment of the establishments HACCP and SSOP procedures
- _____ Develops, documents, and implements a verification plan
- _____ Conducts verifications to evaluate the effectiveness of corrective actions

Attachment 1

***Salmonella* Ground Sampling (05A03)**

It is important to have good aseptic sampling techniques and follow the step-by-step procedure when sampling. The procedure FSIS personnel use to collect samples for *Salmonella* testing is the same aseptic procedure used by plant personnel to collect carcass sponge samples. Information regarding sampling is available in FSIS Directive 10,230.5, Amendment 1, and the questions and answers section of FSIS Directive 10,011.1 (Attachment 2 of this module).

If an establishment has an antimicrobial spray as a CCP in their HACCP plan, carcass samples are taken after the spray and prior to packaging or cut-up. If poultry carcasses are cut up prior to entering the chill tank, any equivalent pieces that make a whole bird can be selected and sampled for *Salmonella* testing. Ground product samples are collected after grinding and before final packaging. When possible, samples should be collected before spices or seasonings are added.

The sample location and time for the product identified for sampling (beef, chicken, or turkey) are randomly selected. The sampling area is sanitized. The FSIS sampler must wash and sanitize hands and arms to the mid-forearm, and then dry them.

Open the Whirl-Pak® filter bag identified with a pink fluorescent label and set it aside. Open the sterile bag containing the 25 gram sample ring is push the plastic-wrapped ring up to the top of the bag without touching the plastic wrap or the inner surface of the bag. Then the bag and its contents are set aside on a sterile surface.

The sampler puts on the sterile gloves. The sampler then removes the sterile plastic-wrapped ring template from the bag, without touching the outside of the bag or any other nonsterile surface.

The sterile tape or seal on the plastic wrap is opened. The ring is unwrapped. The sterile sheet is placed on the sanitized work surface. The ring is placed in the center of the wrap.

Without touching anything but the sample and the ring, the sampler collects enough raw ground product to fill the ring. Ground product is selected from various portions of the batch to ensure that the sample is representative of the product. On a sterile surface the sample is firmly packed into the ring, eliminating air pockets. The sample is packed until it is even with the top of the ring. The rings are designed to collect 25 grams of product, the required sample size for the laboratory analysis.

The filled ring is lifted from the sheet and held over the open Whirl-Pak bag. With a gloved finger the sampler pushes the ground product out of the ring into the bag. Do not include the ring with the sample or the sample will be discarded.

Excess air is expelled and the top of bag is folded over 3 to 4 times. It is sealed.

Attachment 2

(FSIS Directive 10,011.1 Attachment 1)
QUESTIONS AND ANSWERS (with Updates)

1. **Question:** How do inspection personnel know when to begin *Salmonella* sampling?

Answer: The Food Hazard Surveillance Division of OPHS will schedule plants and products for *Salmonella* sampling. If a plant has been selected for sampling, headquarters sends inspection personnel FSIS Form 10,210-7 and the FSIS Laboratory sends the sample boxes and supplies. Upon receiving the supplies and forms, inspection personnel review the sampling guidebook provided with FSIS Directive 10,230.5 and begin sampling.

2. **Question:** Why are more sample request forms received than needed to complete a sample set?

Answer: Occasionally, samples must be discarded upon arrival at the laboratory. Reasons for discards include, but are not limited to, leaking and delays in transit by the courier. The extra forms will be used to submit samples to replace any discarded samples. If a sample set is completed before running out of forms, return any unused forms to the laboratory indicated on the form via regular U.S. Mail.

3. **Question:** What should the IIC do if they run out of sample request forms but have not been notified that the sample set is complete?

Answer: Additional forms may be obtained by sending a message through Outlook using the following address: Sampling Forms-Headquarters

4. **Question:** Is it permissible for the establishment to take a companion sample to the FSIS *Salmonella* sample each day?

Answer: Yes. For chicken whole bird rinses, it is permissible to give the establishment the remainder of the rinse fluid after the 30 ml has been poured into the sample container. For sponge samples of cattle, swine, or turkey carcasses the **entire** sponge and BPW must be sent to the FSIS laboratory. The establishment may take its own sponge sample from the same carcass, or a 25g sample of ground product from the same lot. In any case, the FSIS laboratory result is the official result for regulatory purposes.

5. **Question:** Should samples be collected for pork sausage or turkeys even though there is no performance standard for these products?

Answer: Yes. If scheduled, these products are being tested under pre-implementation testing until the performance standards are established.

6. **Question:** What does an IIC do if instructed to sample for a specific product not produced at all by the establishment?

Answer: Send the forms to the laboratory, marking one form in the code 60 "Product not Produced" box. Indicate what products are produced in that establishment to assist in planning future sampling.

7. **Question:** What does an IIC do if instructed to sample product that is rarely produced by the plant?

Answer: If the plant **typically** produces this product less than 26 times per year, return the forms to the laboratory with a note indicating this. An establishment is exempt if **all ground product** is subsequently used in a product that does not meet the standard of identity found in 9 CFR 319.15(a) and (b).

In order to be exempt from testing, meat slaughter establishments must kill less than 500 head annually of a specific type of livestock, and must slaughter a minimum of 100 different days during the year.

In order to be exempt from testing, chicken slaughter establishments must kill less than 20,000 young chickens annually.

If an establishment is an infrequent producer, put a check mark in code 72 on an FSIS Form 10,210-7. Write the reason samples are not collected on the back of the form. Return all the forms to the originating laboratory indicated on the form.

8. **Question:** If an establishment produces ground beef every day and ground pork one day per week, why do the sample request forms indicate to sample ground pork?

Answer: The product indicated on the sample request forms is either randomly selected by the computer system or is a product being targeted by FSIS for sampling in any establishment producing that product. As long as the establishment is not identified as an infrequent producer, as explained in question 7, product should be sampled. Any other raw product produced by that establishment and covered by a performance standard may be selected for sampling at a later date.

9. **Question:** If an establishment only produces the requested product on the second shift, which is too late for Federal Express pickup, should a sample be collected?

Answer: Yes. It is very important that all shifts, rails, chillers, coolers, and grinders have an equal chance of being selected for sampling. The IIC should coordinate the collecting and mailing of samples that occur during different shifts. Late production can be sampled, provided the following guidelines are followed:

Carcasses – If a carcass sponge (cattle, swine, or turkey) or chicken rinse sample cannot be shipped the same calendar day it was collected, randomly select the carcass for sampling and hold it, refrigerated. The sponge sampling or chicken rinse procedure is to be completed the next business day that overnight shipping can occur. The collection date, as recorded on FSIS Form 10,210-7, is the date on which the carcass is sponged or rinsed. **Remember: the sponge or rinse sample must be shipped on the day it is collected.**

Ground Product – Ground product samples can be held refrigerated until overnight courier can ship the sample.

10. **Question:** If an establishment only slaughters cattle (or swine) one day per week and the carcasses will not be in the cooler for at least 12 hours before the inspector's shift is over, does he/she have to return to the establishment the next day to perform the sample?

Answer: Yes, if at all possible, within the normal constraints of assignment and tour of duty. If this is not possible, collect and submit the sample on the same day as slaughter. These situations should be discussed with your supervisor. Additional guidance will be provided on a case-by-case basis by the TSC.

11. **Question:** Is mechanically separated product covered?

Answer: Not at this time. The definitions of the ground products covered under this testing program can be found in FSIS Notice 21-98, 6/9/98.

12. **Question:** How can the plant receive their sample set results by e-mail?

Answer: Plant management can get an FSIS Form 10,230-2 from the DO and fax it to **202-501-0369**. Results will then be forwarded to the e-mail address upon completion of a sample set.

13. **Question:** Page 3-2 of the *Salmonella* Guidebook specifies that partially skinned hogs can be sampled. Are fully skinned hogs eligible for sampling?

Answer: Yes. All fully-skinned swine carcasses, except sows and boars, may be sponge sampled.

14. **Question:** In addition to *Salmonella* compliance and pre-implementation testing, are other raw product samples being collected that may involve *Salmonella* testing?

Answer: Yes, the Microbiological Baseline Testing Programs. The following List is general information about these programs.

- The baseline programs are species-specific and generally last one year.
- Inspection personnel use FSIS Form 10,210-2.
- FSIS Form 10,210-2 indicates the week that the sample is to be collected.
- Inspection personnel follow sample collection procedures indicated on the form.
- The baseline programs are non-regulatory and no regulatory action will be taken.
- Results may be used to establish future *Salmonella* performance standards.
- The programs may include multiple samples and laboratory analyses.

Also, from time to time samples may be requested for *Salmonella* (or other organism) analyses for special projects/studies. Inspection personnel may use FSIS Form 10,210-2 or FSIS Form 10,210-3. Specific instructions for the study will be provided.

If sample request forms are received for both HACCP (compliance or pre-implementation) AND baseline samples, take samples according to the following priority, as time permits:

1. HACCP Compliance

2. Microbiological baseline

15. **Question:** How do inspectors document the *Salmonella* sampling procedure?

Answer: *Salmonella* sampling is a directed sampling procedure. It is documented as an unscheduled 05A03 on the process schedule and recorded as performed. NR's are not written for noncompliance. Rather, the noncompliance is a trigger to FSIS employees to assess the effectiveness of the HACCP and SSOP systems.

16. **Question:** If an establishment grinds a product covered by a performance standard but then uses it to make fully cooked product, is the raw ground product sampled?

Answer: No. Ground product is only sampled if it leaves the establishment in the raw state. If the raw ground product is processed into a ready-to-eat product prior to leaving the establishment it is not sampled.

17. **Question:** Should the District Manager contact an establishment before a sample set is complete and, if so, when?

Answer: District Managers are required to notify an establishment as soon as the number of positive samples exceeds 50% of the total test failures that constitute a set failure. The purpose of the notification before the set is complete is to promote early corrective actions that will reduce pathogen levels.

18. **Question:** If a plant produces coarse ground beef for sale in 10-pound chubs and also produces a product labeled "100% veal patties," does it matter which product is sampled?

Answer: All ground beef and veal products produced and shipped from the plant that meet the definition stated in FSIS Notice 21-98 are subject to sampling. In short, if product meets 9 CFR 319.15 (a) or (b), it is subject to sampling. Both types of ground product should have an equal chance of being selected when daily samples are collected. Also, the random selection should occur across all shifts.

Salmonella Regulations, Livestock, 310.25(b) and Poultry, 381.94(b)

Sec. 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standard; *Salmonella*. (1) Raw meat product performance standards for *Salmonella*. An establishment's raw meat products, when sampled and tested by FSIS for *Salmonella*, as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

Table 2--*Salmonella* Performance Standards

Class of product	Performance Standard (percent positive for <i>Salmonella</i>) ^a	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers.....	1.0%	82	1
Cows/bulls.....	2.7%	58	2
Ground beef	7.5%	53	5
Hogs.....	8.7%	55	6
Fresh pork sausages.....	^b N.A.	N.A.	N.A.

a Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.

b Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.

 \3\ A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

- (i) The establishment shall take immediate action to meet the standard.
- (ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.
- (iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted

tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

Sec. 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standards; *Salmonella*.

(1) Raw poultry product performance standards for *Salmonella*. (i) An establishment's raw poultry products, when sampled and tested by FSIS for *Salmonella* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

Table 2.--*Salmonella* Performance Standards

Class of product	Performance Standard (per cent positive for <i>Salmonella</i>) ^a	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers.....	20.0%	51	12
Ground chicken.....	44.6	53	26
Ground turkey.....	49.9	53	29
Turkeys.....	^b N.A.	N.A.	N.A.
Squabs.....	^b N.A.	N.A.	N.A.
Ratites.....	^b N.A.	N.A.	N.A.

^a Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.)

^b Not available; baseline targets for turkeys, squabs, or ratites will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.\3\

 \3\ A copy of FSIS's ``Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

- (i) The establishment shall take immediate action to meet the standard.
- (ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.
- (iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.